

REMARKS

This Amendment is submitted in reply to the final Office Action mailed on April 22, 2008. No fee is due in connection with this Amendment. The Director is authorized to charge any fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-753 on the account statement.

Claims 1-21 are pending in this application. Claims 9-11 and 15-19 were previously withdrawn. In the Office Action, Claims 1-8, 12-14 and 20-21 are rejected under 35 U.S.C. §103. In response, Claims 1, 12 and 14 have been amended. The amendments do not add new matter. In view of the amendments and/or for the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 1-8, 12-14 and 20-21 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,925,394 to Levinson ("Levinson") in view of U.S. Patent No. 7,108,887 B2 to Chu et al. ("Chu"). In response, Applicants have amended Claims 1, 12 and 14. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that the cited references fail to disclose or suggest every element of the present claims.

Currently amended independent Claim 1 recites, in part, a primary composition comprising at least essential lipophilic and hydrophilic bioactive components of a material selected from the group consisting of whole fruit, vegetable and plant material, excluding insoluble fibers, with improved bioavailability, miscibility and stability in a carrier selected from the group consisting of milk, milk protein-containing carriers and combinations thereof, wherein the essential lipophilic and hydrophilic bioactive components are extracted from the material using the milk or milk protein-containing carrier. Similarly, currently amended independent Claims 12 and 14 recite, in part, a primary composition comprising at least essential lipophilic and hydrophilic bioactive components of a material selected from the group consisting of whole fruit, vegetable, and plant material, excluding insoluble fibers, and combinations therof, with improved bioavailability, miscibility and stability in a milk or milk protein-containing carrier, wherein the essential lipophilic and hydrophilic bioactive components are extracted from the material using the milk or milk protein-containing carrier. These amendments do not add new matter. These amendments are supported in the Specification at, for example, paragraph 8, lines

1-6; paragraph 19, lines 1-8; paragraph 20, lines 1-5; paragraph 25, lines 7-9; paragraph 34, lines 1-8; paragraph 35, lines 4-5; paragraph 50, lines 1-15; paragraph 51, lines 1-9; paragraph 58, lines 1-12; paragraph 61, lines 1-7; and paragraph page 4, lines 3-5 and 13-17; page 5, lines 14-17; page 6, lines 16-22 and 26-32; page 11, lines 4-10, lines 1-14.

Essential bioactive components extracted from fruits or plant materials are well-known and widely used in the food industry. See, Specification, paragraph 2, lines 1-3. However, conventional techniques for extracting such bioactive components only extract some of the bioactive components from the fruit or plant material. See, Specification, paragraph 6, lines 1-7. For example, water extraction techniques, in which the bioactive components are extracted from insoluble fibers, preserve the natural image and nutritional functions of the bioactive components but are not very efficient. See, Specification, paragraph 4, lines 8-10. Solvent extraction techniques, while more efficient than water extraction, still fail to extract a substantial portion of the bioactive components from the fruit or plant material and simultaneously impair the nutritional functions of the bioactive components. See, Specification, paragraph 4, lines 9-10; paragraph 5, lines 8-11; and paragraph 6, lines 1-7. Therefore, the essential bioactive components of the present claims are extracted from fruits or plant materials using a milk or milk protein-containing carrier. See, Specification, paragraph 19, lines 5-8; and paragraph 34, lines 1-8. The fruit or plant material is mixed in a milk or milk protein-containing medium and separated from insoluble fibers to obtain an aqueous suspension. See, Specification, paragraphs 12-17. By using a milk or milk protein-containing carrier to extract the bioactive components from the fruit or plant material, the present claims provide bioactive components with improved miscibility, stability and bioavailability over conventional extraction techniques without the use of organic solvent residues. See, Specification, paragraphs 4-8 and 18-19. Furthermore, by also removing the insoluble fibers, the primary composition of the present claims can be efficiently produced. See, Specification, paragraph 18. In contrast, the cited references are deficient with respect to the present claims.

Even if combinable, the cited references fail to disclose or suggest a primary composition comprising at least essential lipophilic and hydrophilic bioactive components of a material selected from the group consisting of whole fruit, vegetable, and plant material, excluding insoluble fibers, and combinations thereof, with improved bioavailability, miscibility and stability as required, in part, by currently amended independent Claims 1, 12 and 14. Levinson is

entirely directed to denatured foam food products such as whipped milk products. See, *Levinson*, Title; Abstract, lines 1-2 and 8-13. The denatured foam products are formed by whipping or otherwise denaturing protein food products such as whole milk, skim milk, evaporated milk and reconstituted milk powder to form a stable foam milk product. See, *Levinson*, Abstract, lines 1-13. Nowhere does *Levinson* disclose or suggest essential lipophilic and hydrophilic bioactive components with improved bioavailability, miscibility and stability over that obtained using conventional extraction techniques, nor does the Patent Office cite support for such claimed element.

The Patent Office asserts that *Levinson* discloses freshly squeezed grapefruit juice mixed with milk products and, as such, inherently discloses lipophilic bioactive components in a milk or milk protein-containing carrier. See, Office Action dated September 26, 2007, page 3, lines 16-21. However, nowhere does *Levinson* disclose that the lipophilic bioactive components have improved bioavailability, miscibility and stability, nor does the Patent Office cite support for such claimed element. In fact, *Levinson* fails to even use the term "bioactive components." The primary composition of the present claims provides bioactive components with improved bioavailability, miscibility and stability by extracting bioactive components from a fruit or plant material using a milk or milk protein-containing carrier instead of an organic solvent. See, Specification, paragraphs 5 and 18-19. In contrast, *Levinson* is entirely directed to denatured foam products such as whipped milk products. See, *Levinson*, Abstract, lines 8-13. Although the whipped milk products may be combined with fruit juices, see, *Levinson*, Abstract, lines 8-13, *Levinson* fails to disclose extracting bioactive components from the fruits or fruit juices using the milk product. As such, *Levinson* fails to disclose or suggest essential lipophilic and hydrophilic bioactive components with improved bioavailability, miscibility and stability in accordance with the present claims.

The Patent Office relies on *Chu* merely for the disclosure of removing insoluble fibers from a fruit. See, Office Action dated September 26, 2007, page 4, lines 8-20. As the Patent Office admits, *Chu* is entirely directed to separating a citrus juice source into a liquid and a retentate containing pulp. See, Office Action dated September 26, 2007, page 4, lines 9-11. Nowhere does *Chu* disclose or suggest essential lipophilic and hydrophilic bioactive components with improved bioavailability, miscibility and stability, nor does the Patent Office cite support for such claimed element. Therefore, the cited references fail to disclose a primary composition

comprising at least essential lipophilic and hydrophilic bioactive components of a fruit, vegetable or plant material, excluding insoluble fibers, with improved bioavailability, miscibility and stability as required, in part, by the present claims.

Moreover, the cited references fail to disclose or suggest a primary composition wherein the essential lipophilic and hydrophilic bioactive components are extracted from the material using the milk or milk protein-containing carrier as required, in part, by independent Claims 1, 12 and 14. As discussed previously, *Levinson* fails to disclose or suggest extracting bioactive components from a fruit or plant material using a milk product. Furthermore, *Chu* is entirely directed to separating a citrus juice source into a liquid and a solid portion and further processing the liquid to remove undesirable components. See, *Chu*, column 1, lines 15-21. Nowhere does *Chu* disclose extracting the bioactive components from the citrus juice source using a milk product. Thus, the cited references fail to disclose or suggest a primary composition wherein the essential lipophilic and hydrophilic bioactive components are extracted from the material using the milk or milk protein-containing carrier as required, in part, by independent Claims 1, 12 and 14 and Claims 2-8, 13 and 20-21 that depend therefrom.

Applicants note that the claimed element of improved bioavailability, miscibility and stability of the bioactive components has been added primarily because the Patent Office seemed to suggest that such a limitation may make the claims allowable over the cited references. Applicants do not believe that such a limitation is necessary because it is inherent in the present claims. By extracting the essential lipophilic and hydrophilic bioactive components from the fruit or plant material using a milk or milk protein-containing carrier, the bioavailability, miscibility and stability of the bioactive components is improved over conventional extraction techniques. See, Specification, paragraphs 4-8 and 18-19. As such, because the present claims recite, in part, a primary composition wherein the essential lipophilic and hydrophilic bioactive components are extracted from the material using the milk or milk protein-containing carrier, the essential lipophilic and hydrophilic bioactive components necessarily have improved bioavailability, miscibility and stability. For reasons discussed previously, the cited references fail to disclose every element of the present claims.

Furthermore, one of ordinary skill in the art would have no reason to combine the cited references because *Levinson* teaches away from *Chu* and the present claims. In this regard, references must be considered as a whole and those portions teaching against or away from each

other and/or the claimed invention must be considered. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve Inc.*, 796 F.2d 443 (Fed. Cir. 1986). “A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the Applicant.” *Monarch Knitting Machinery Corp. v. Fukuhara Industrial Trading Co., Ltd.*, 139 F.3d 1009 (Fed. Cir. 1998), quoting, *In re Gurley*, 27 F.3d 551 (Fed. Cir. 1994).

Levinson is entirely directed to denatured food products, including denatured milk products. See, *Levinson*, Abstract, lines 8-13. The denatured milk products are formed by denaturing certain denaturable protein food products such as whole milk, skim milk, evaporated milk and reconstituted milk powder. See, *Levinson*, Abstract, lines 1-5. These un-denatured products may be formed into the whipped products of *Levinson* by concurrently denaturing and whipping the products into a foam. See, *Levinson*, Abstract, lines 8-9. The products may be denatured by heating, altering the pH, or mechanically agitating the denaturable product. See, *Levinson*, column 5, lines 25-27. A “denatured” product is defined as a product that is “made unnatural or changed from the normal in any of its characteristics; often applied to proteins or nucleic acids heated or otherwise treated to the point where tertiary structural characteristics are altered.” Biology-Online Definition of “denatured,” <http://www.biology-online.org/dictionary/Denatured>. As such, the denatured products of *Levinson* are altered or changed from the characteristics of the original whole milk, skim milk, evaporated milk or reconstituted milk powder.

In contrast, the present claims are entirely directed to non-denatured milk or milk-protein containing carriers for extracting bioactive components from a fruit or plant material. See, Specification, paragraph 33. For example, “[t]he milk carrier may be in the form of skinned milk or whole milk from animal or plant origin (e.g. soymilk, juice or coconut milk, etc.).” See, Specification, paragraph 33, lines 4-6. Therefore, the denatured milk products of *Levinson* teach away from the milk or milk protein-containing carriers of the present claims.

Furthermore, *Levinson* teaches that any fruit added to its denatured milk product is added as a whole, including insoluble fibers. For example, additives such as fruit, including bananas, pears, apples, and berries, are added to the denatured milk product in sizes such as those present in strawberry jam and shredded coconut. See, *Levinson*, column 12, lines 22-36. As the

Examiner admits, *Levinson* fails to disclose or suggest removing the insoluble fibers before adding the fruit to the denatured milk product. See, Office Action dated September 26, 2007, page 4, line 8. In contrast, *Chu* discloses separating or removing the solids from its liquid juice product. See, *Chu*, column 1, lines 15-25. The present claims similarly teach excluding the insoluble fibers from the extracted bioactive components. See, Specification, paragraphs 9 and 14.

The Patent Office asserts that the references must be considered as a whole and cannot be attacked individually. See, Office Action, page 3, lines 8-10. However, Applicants respectfully submit that the Patent Office must consider those portions of the references teaching away from each other and/or the present claims. As such, *Levinson* teaches away from both *Chu* and the present claims by disclosing that the fruit should be added as a whole without excluding the insoluble fibers. Therefore, Applicants respectfully submit that one of ordinary skill in the art would have no reason to combine *Levinson* with *Chu* to arrive at the present claims.

Applicants note that Patent Office specifically stated in the Office Action dated September 26, 2007 that the *Borradaile*, *Lee*, and *Gorinstein* references were merely cited “to relay an intrinsic property and [are] not used in the basis for rejection *per se*. See, Non-Final Office Action dated September 26, 2007, page 5, lines 7-8. As such, Applicants have not addressed these references.

Accordingly, Applicants respectfully request that the rejection of Claims 1-8, 12-14 and 20-21 under 35 U.S.C. §103(a) to *Levinson* in view of *Chu* be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Patent Office is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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